Representative Henry A. Waxman
Seminar on "Intellectual Property and Access to Medicines: The importance of reaching a balance between innovation and access"
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Bienvenidos. Let me start by welcoming all of you to Washington for a timely discussion about international trade policy and public health.

The impact of high drug prices on access to medicines is being felt in all corners of the world. In developing countries in particular, many are dying of diseases even though highly effective, life-saving drugs exist.

Yet, behind closed doors, the Bush Administration has been working to restrict the ability of our trade partners to acquire low-cost generic medicines that could treat these patients. Following the wishes of the brand name industry, this Administration has used trade negotiations to demand intellectual property rules that result in keeping drug prices as high as possible for as long as possible.

These rules go beyond the basic requirements of the World Trade Organization. They also go against the Doha Declaration, which was adopted by the WTO in 2001. The purpose of the Doha Declaration was to make clear that trade obligations should not undermine the ability of governments to promote access to medicine and address public health needs.

The U.S. Congress endorsed the Doha Declaration and directed the President to respect its principles as a primary objective in trade negotiations.

Unfortunately, what we have seen in practice from the U.S. Trade Representative is the exact opposite. For example, recent agreements with developing countries require patent extensions to compensate for delays in the approval of a patent or a drug application.

The agreements prohibit the approval of generic medicines for five years after a drug is first introduced, even if the patent has already expired. They also require health authorities to link decisions about drug approval to a drug's patent status.

The consequence is that developing nations, which need lower cost drugs the most, will now have to wait the longest to obtain them.

In Latin America the challenges are especially difficult because U.S. free trade agreements have created a complicated web of different rules in different countries. As a result, we may now face situations where a generic medicine available in Mexico cannot be approved for sale next door in Guatemala. Or a generic medicine made in Argentina might be kept off the market in neighboring Chile for several years. In some cases these rules could even cause situations where developing countries wait even longer than the United States for access to affordable medicines.

The Bush Administration has insisted that it is only pursuing these additional intellectual property standards on the basis of a U.S. law that is commonly known as "Hatch-Waxman."

As an author of this legislation, I will be the first to tell you that I am very proud of its achievements. It was a carefully crafted compromise that has been highly successful in both promoting generic competition in the United States and stimulating innovation of new drugs. But I will also be the first to say that it is <u>wrong</u> to impose a system like Hatch-Waxman in developing countries.

Many of our trading partners face vastly different challenges and circumstances than we do here in the United States.

Devastating epidemics, including AIDS, TB, and malaria are crippling health care systems and societies. Even in middle-income countries, leading killers like heart disease, diabetes, cancer and other conditions are going untreated because essential medications are unaffordable, costing many times the average citizen's annual income.

The U.S. faced nothing like these kinds of problems when Hatch-Waxman was enacted. If we had, the solution would certainly not have looked like Hatch-Waxman, which delays market entry of low-cost generic drugs for years after a life-saving drug becomes available.

That system works in this country because most people in the U.S. have health insurance that pays for essential drugs. And, the U.S. market is large enough to justify a period of monopoly pricing where innovator companies can recover the cost of their research and development to invest in new cures.

Imposing such a system on countries where people generally lack health insurance could deprive millions of people of life-saving drugs. It is irresponsible and even unethical, especially considering that many of these markets are so small that the profit incentive for innovator companies simply doesn't add up.

You also have to consider that in 1984, when we fought to enact Hatch-Waxman, the FDA had no authority to approve generic versions of new drugs. Hatch-Waxman actually took away monopoly rights from the brand-name drug industry by expanding access to generic drugs.

In contrast, in most developing countries, generic drugs are already widely available. In fact, they are typically the only drugs people in these countries can afford. Imposing Hatch-Waxman in these countries will actually undermine generic competition and benefit only the brand-name drug companies.

The bottom line is that the U.S. Trade Representative is seriously mistaken to view Hatch-Waxman as a "one-size-fits-all" policy. What is worse, a new report by the Government Accountability Office shows that USTR doesn't even examine the potential public health impacts of its demands.

Senator Kennedy and I asked the GAO, an independent watchdog arm of Congress, to examine how USTR has interpreted and implemented the congressional mandate to respect the Doha Declaration.

Among its key findings, the GAO found that the U.S. made virtually no changes to its trade strategy in connection to the Doha Declaration. The report also shows that the U.S. has narrowly interpreted the declaration and sought to limit its application to epidemics rather than permitting countries to assess their own public health priorities. And, the report indicates that the public health community has little input into the development of our trade policies.

The good news is that we are finally turning a corner. First, we are succeeding in raising awareness of the issue. We've always heard people talk about the impact of trade on labor and the environment and now people are talking about health as well.

Second, we are starting to undo the damage caused by the Bush Administration. The trade agreement with Peru is a key example. After the Democratic Party took control of Congress in the last election we were able to pressure the President to significantly change the agreement and reduce the impact on public health. Congress has also decided not to renew the President's authority to negotiate any more trade agreements before he leaves office.

The next step is to use the momentum to move the issue even further.

We need to look for ways to give public health organizations more input on U.S. trade strategy. We need to examine whether it is possible to renegotiate some of the strictest agreements like CAFTA so that they too can benefit from the revised standards in the FTA with Peru.

Most importantly, we have to stand firm and make clear that public health is not a commodity that can be traded away.

I welcome the opportunity to work with you and your governments to find solutions that expand access to medicines and make our countries healthier and more prosperous places to live.